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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,834	06/26/2000	Michael Kraus	39727/DBP/E43	2410

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/603,834

Applicant(s)

KRAUS ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 1 and 21, the claimed element, “a fixed time interval ratio”, is not found in the instant specification, nor does the specification appear to disclose how “the fixed time interval ratio” is used to impact the data transmission.

In claims 1 and 21, the claimed elements of “periodically” beginning data transmission “at the end of a first pre-determined time interval” and maintaining reception readiness “for a second pre-determined time interval” are not found in the instant specification, nor does the specification appear to disclose how these elements are used to impact the data transmission.

3. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of claims 1 and 21 are unclear because a comparison of the time intervals is claimed to reflect a ratio, but the actual step of comparing the interval is not claimed and the impact of the comparison on the telemetry process is indefinite.

Claim Rejections - 35 USC § 102

4. Claims 1-3, 6, 7, 16, and 19-22 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nappholz et al. (US 5113869). Nappholz et al. disclose an implantable ambulatory monitor. The telemetry receiver/transmitter performs two-way, digital telemetry to transfer data and programs between the implant and an external device. (col. 16 @ 25-27). The microprocessor of the implant triggers communication with an external device using a beacon signal indicating the reception readiness of the implant, and uses two intervals to control the receiving portion of the implant receiver/transmitter (col. 16 @ 61 – col. 17 @ 6). The reception readiness of the implant is controlled by the synchronization sequence, read as “at least one first item”, sent by the external device (col. 17 @ 13-47). The external receiver/transmitter is substantially permanently ready for data exchange (col. 17 @ 22-25). The implant initiates communications with an external device to provide a warning about abnormal conditions or about implant malfunction (col. 16 @ 34-44). Data communications can be initiated by the implant (col. 21 @ 31-43).

The Applicant's arguments filed 2/5/03 have been fully considered, but they are not convincing.

The Applicant amended independent claims 1 and 21 to periodically begin data transmission at the end of a predetermined time interval and argues Nappholz et al. only initiate data transmission on the detection of a condition. The Examiner disagrees. Nappholz et al. disclose that data transmission is periodically initiated when the memory of the implanted device is full, on an approximately 10 minute cycle, hence Nappholz et al. is read to periodically begin

data transmission at the end of a predetermined time interval, the predetermined interval being the time interval associated with a full implanted device memory (col. 21 @ 31-43).

The Applicant amended independent claims 1 and 21, noting a comparison of the ratio of the time intervals of the transmitters/ receivers indicates energy savings. It is inherent that a reduction in the (ratio of) operational time of the communication link is reflected in less energy usage by the device. Nappholz et al. is aware of energy saving associated with a reduction in operating time, stating communication is performed in a burst mode to conserve the energy of the implanted device (col. 21 @ 31-33).

Claim Rejections - 35 USC § 103

5. Claims 4, 8-15 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of de Coriolis (EPO 0607638). As discussed in paragraph 4 of this action, Nappholz et al. disclose the claimed invention except for:

- the triggering signal including a first data set (claim 4),
- implementing a first plausibility check (claim 8),
- implementing renewed transmissions if the power supply is not exceeded (claim 9),
- checking the data (claim 10),
- sending a second acknowledgement (claim 11),
- implementing a second plausibility check (claim 12),
- effecting a new transmission when a defective transmission is established (claim 13),
- effecting renewed transmission after expiry of a waiting time period (claim 14),
- after renewal of the transmission, repeating the method steps (claim 15), and

- upon non-reception of transmissions, prolonging the transmission (claim 17).

De Coriolis discloses a telemetry system for an implantable device including an implant device receiver (44) and transmitter (46) and an external programmer receiver (32) and transmitter (34). The telemetry circuit is used intermittently and contains a wakeup command transaction to enable full activation of the telemetry means (28) (col. 10 @ 49-59). During periods of quiescence, the telemetry means, at spaced apart time intervals, enters a partially active state to detect energy transmissions. If energy is detected, further detection occurs seeking the transmitted initiation command. Once the initiation command is detected, the telemetry system becomes fully active, the receiver sends a response code and the communication transaction begins (col. 11 @ 1-22; col. 20 @ 14-26). The outbound data packet is grouped in fixed length frames, read as intervals, with a preamble (58), a data field (62), a control byte (64), a frame check (containing error code to trigger resending of the data, read as a first acknowledgment) and a postamble (68) used for error detection (col. 12 @ 9-33). The inbound data packet contains a leading flag (74), a data field (78), a control byte (76), a frame check (80) (containing error code to trigger resending of the data, read as a second acknowledgment) and a trailing flag (82) (col. 14 @ 2-12). The preamble (58) and the leading flag (74) are read as the triggering signals; this frame contains a first data set and second data set respectively in the data fields. The stay awake signal is read as the waiting time interval (col. 21 @ 37-41). In is inherently understood transmission would not take place in a low battery scenario as therapeutic operations of the implant take priority.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by Nappholz et

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al., with the specifics of the signal modulation and system component interaction to enable signal transmission as taught by de Coriolis so a known and proven means of signal modulation and system component interaction is adopted to enable data transfer between the implanted device and the remote external unit so the patient's condition can be evaluate the patient's care optimized.

6. Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of Fountain et al. (US 4625730). As discussed in paragraph 4 of this action, Nappholz et al. disclose the claimed invention except for the triggering signal being initiated by the wearer.

Fountain et al. disclose an ECG recording controller and teach that it is known to provide a manual means for initiating a triggering pulse to begin a transmission when the patient perceives an emergency situation (abstract; col. 6 starting @ 23). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by Nappholz et al., with the manually initiated emergency signal as taught by Fountain et al. to provide a system with a means that enables the patient to get help when he perceives help is needed.

7. Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of Wyborny et al. (US 5354319). As discussed in paragraph 4 of this action, modified Nappholz et al. disclose the claimed invention except for the intervals varying in length.

Wyborney et al. disclose a telemetry system and teach that it is known to use variable interval lengths (col. 5 @ 53-58). Therefore it would have been obvious to one having ordinary

skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by Nappholz et al., with the variable interval lengths as taught by Wybroney et al. to compress the frame length so more data can be transmitted in a fixed time.

Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JFO
3/30/03

Angela D. Sykes

ANGELA D. SYKES
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